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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/765,606	01/22/2001	Hiroshi Nojiri	202135US0	9738

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EXAMINER

BERMAN, ALYSIA

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 08/14/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/765,606

Applicant(s)

NOJIRI ET AL.

Examiner

Alysia Berman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 May 2002 and 28 May 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 8, 11 and 14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 10 and 13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-13 are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2, 8.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

Receipt is acknowledged of the amendment filed May 20, 2002 and the information disclosure statement filed May 28, 2002. Claim 1 has been amended. Claims 3-14 have been added. Claims 1-14 are pending.

Election/Restrictions

Newly submitted claim 14 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: original claims 1 and 2 are directed to a composition, which is an independent and distinct invention from the method of claim 14.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 14 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

This application contains claims directed to the following patentably distinct species of the claimed invention: amino acids, urea and glycinebetaine.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 2, 4-6, 9 and 12 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim

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is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

During a telephone conversation with Richard Chinn on June 7, 2002 a provisional election was made with traverse to prosecute the invention of amino acids, claims 3, 7, 10 and 13. Affirmation of this election must be made by applicant in replying to this Office action. Claims 8 and 11 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

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remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Specification

The title of the invention is not descriptive. The Examiner acknowledges applicant's response in the amendment filed May 20, 2002, paper no. 7, to the objection to the title in the Office Action mailed December 20, 2001, paper no. 4. Although the Examiner may have the authority to change the title at the time of allowance, it is applicants' responsibility to provide a descriptive title. Applicant is required to provide a new title that is clearly indicative of the invention to which the claims are directed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 4, 7, 10 and 13 are rejected under 35 U.S.C. 102(e) as being anticipated by JP 316550 (550).

JP '550 discloses compositions comprising arginine and various plant extracts including peony extract and tea extract. The compositions contain 0.4 wt.% of arginine and 0.5 wt.% of each plant extract. See the examples beginning at page 14. Applicant discloses at page 6, line 21 to page 7, line 9 of the instant specification that plant extracts containing sesquiterpene alcohols may be substituted for the sesquiterpene alcohols in the instant invention. The plant extracts disclosed by Applicant include tea.

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The plant extracts of JP '550 inherently contain sesquiterpene alcohols as instantly claimed.

See also the Napralert citations of Lin et al., Analysis of the Aroma of Sichuan Oolong Tea, You-Ji Hua Hsueh (1984) (1):21-24 and Kumar et al., Volatile constituents of Peony Flowers, Phytochemistry (1986), 25(1):250-253, which disclose that both tea extract and peony extract contain the sesquiterpene alcohol nerolidol.

Claims 9 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by RU 2000704 C1 (704).

RU '704 discloses a composition comprising cedar oil, which is the same as cedar wood oil, and amino acids.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-7, 10 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 316550 (550) in view of the Napralert citations of Lin et al., Analysis of the Aroma of Sichuan Oolong Tea, You-Ji Hua Hsueh (1984) (1):21-24 and Kumar et al., Volatile constituents of Peony Flowers, Phytochemistry (1986), 25(1):250-253.

JP '550 teaches all of the limitations of the claims as stated in the 35 U.S.C. 102(b) rejection above. It does not explicitly disclose the sesquiterpene alcohols of claim 2 or the pH of the compositions (claims 5 and 6).

As evidenced by Lin et al. and Kumar et al., the plant extracts contained in the compositions of JP '550 are known to contain sesquiterpene alcohols such as nerolidol. One of ordinary skill in the art would reasonably expect the compositions containing the plant extracts of JP '550 to contain the instantly claimed sesquiterpene alcohols. Burden is shifted to Applicant to show that the compositions of JP '550 do not contain the instantly claimed sesquiterpene alcohols.

It is within the skill in the art to select optimal parameters in a composition in order to achieve a beneficial effect. *In re Boesch*, 205 USPQ 215 (CCPA 198). It would have been obvious for one skilled in the art to vary the proportions of components in a composition to arrive at the best compositions for the intended purpose. "It is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Only if the "results

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optimizing a variable" are "unexpectedly good" can a patent be obtained for the claimed critical range. *In re Antonie*, 559 F.2d 618, 620, 195 USPQ 6, 8 (CCPA 1977); see also *In re Dillon*, 919 F.2d 688, 692, 16 USPQ2d 1897, 1901 (Fed. Cir. 1990) (in banc).

Absent evidence of unexpected results, the pH of the composition is not given patentable weight over the prior art.

It would have been obvious to one of ordinary skill in the art at the time of the invention to prepare the compositions of JP '550 with the reasonable expectation that the compositions would contain the sesquiterpene alcohol nerolidol, which would provide a pleasant aroma to the compositions.

Claims 9 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,419,935 B1 (935).

US '935 discloses a cosmetic skin treating patch (title and abstract). The patch contains a polymeric matrix that contains at least one active agent (col. 2, lines 54-57). Among the active agents disclosed are amino acids (col. 5, lines 12-17). The polymeric matrix may also contain essential oils such as cedar oil (col. 7, lines 23-25).

US '935 does not teach a composition comprising both an amino acid and cedar oil. US '935 does teach that an amino acid and cedar oil may be used in the polymeric matrix compositions for their respective art-recognized properties, cosmetic activity and providing freshness to the skin.

It would have been obvious to one of ordinary skill in the art at the time of the invention to prepare the polymeric matrix of US '935 and add amino acids and cedar oil

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expecting to obtain a cosmetically active composition that provides a feeling of freshness to the skin.

Unexpected Results

It is applicant's burden to demonstrate unexpected results over the closest prior art. See MPEP 716.02, also 716.02 (a) - (g). Furthermore, the unexpected results should be demonstrated with evidence that the differences in results are in fact unexpected and unobvious and of both statistical and practical significance. *Ex parte Gelles*, 22 USPQ2d 1318, 1319 (Bd. Pat. App. & Inter. 1992). Moreover, evidence as to any unexpected benefits must be "clear and convincing" *In re Lohr*, 137 USPQ 548 (CCPA 1963), and be of a scope reasonably commensurate with the scope of the subject matter claimed, *In re Linder*, 173 USPQ 356 (CCPA 1972).

In the instant case, the data presented in Table 1 are not commensurate in scope with the claims. The data supports unexpected results for compositions comprising specific amino acids and oils or sesquiterpene alcohols in amounts that provide unexpected moisturizing effects to the skin. The claims are not limited to compositions that provide unexpected moisturizing effects to the skin by virtue of the combination of amino acids and oils or sesquiterpene alcohols shown in the amounts shown.

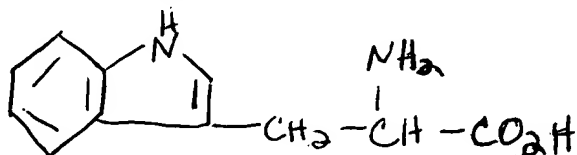
Response to Arguments

Applicant's arguments with respect to claims 1 and 2 have been considered but are moot in view of the new ground(s) of rejection.

Applicant argues that a demonstration of improved moisturizing with the amino acid arginine* is predictive of the moisturizing effects to be observed with other amino

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acids in combination with a sesquiterpene alcohol. Not all amino acids bear close structural similarity. For example, arginine is a branched chain amino acid of the formula $\text{H}_2\text{N}-(\text{CH}_2)_3-\text{NH}-\text{C}(\text{NH}_2)(\text{CO}_2\text{H})-\text{CH}_2-\text{NH}_2$, whereas tyrosine has the formula $\text{H}_2\text{N}-\text{CH}(\text{CO}_2\text{H})-\text{CH}_2-\text{C}_6\text{H}_4-\text{OH}$ and tryptophan has the formula



One of ordinary skill in the art would not necessarily expect amino acids with such different formulas to behave in the same manner when combined with a sesquiterpene alcohol. Therefore, the data showing unexpected results is limited only to those amino acids disclosed.

*Applicant refers to the amino acid alanine in the arguments. However, the compositions provided in Table 1 contain arginine. The Examiner assumes that this is a typographical error and that Applicant's intent was to refer to arginine.

Conclusion

Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on May 28, 2002 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609(B)(2)(i). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.


Correspondence

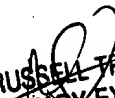
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alysia Berman whose telephone number is 703-308-4638. The examiner can normally be reached Monday through Friday between 9:00 am and 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Russell Travers, can be reached on 703-308-4603. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 or 703-872-9307 for after-final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234 or 703-308-1235.


Alysia Berman
Patent Examiner
August 8, 2002


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